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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,068	05/29/2002	Hans Sigrist	Q68066	6054

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SUGHRUE MION, PLLC  
2100 PENNSYLVANIA AVENUE, N.W.  
WASHINGTON, DC 20037

EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
1637	10

DATE MAILED: 07/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application N .

10/031,068

Applicant(s)

SIGRIST, HANS

Examiner

Suryaprabha Chunduru

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-- The MAILING DATE of this communication appears in the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. Applicants' response to the office action and amendment (Paper No. 9) filed on April 22, 2003 has been entered.
2. Claims 1-19 are pending. New claim 20 is added (Paper No. 9). Claims 1-20 are considered for examination in this office action.

*New issues*

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

A. Regarding claim 5, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

B. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim 1 recites "a physical parameter" which is indefinite because it is unclear whether a physical parameter refers to mass or any other physical parameter other than mass. Further claim 2 recites "said physical parameter can be measured is absorption of light wave or emission of a fluorescence signal" which is unclear whether physical parameter refers to mass or absorption of light wave or emission of a fluorescence signal. Amendment to recite the specific physical parameter would obviate the rejection.

C. Claim 2 recites the limitation "said physical parameter " in sensor system. There is insufficient antecedent basis for this limitation in the claim. Physical parameter in claim 1 is

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recited as mass, and the physical parameter in claim 2 is other than mass that is absorption of a light wave or emission of a fluorescence signal. Thus the said physical parameter is not the same as recited in the claim 1 and therefore the limitation in the claim 2 lacks antecedent basis.

D. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim 1 recites "catalytic units which catalyze" which is unclear and indefinite. It is unclear because whether catalytic units refer to enzymes like exonucleases, endonucleases, ligases, polymerases or enzymes involved in a biochemical reaction (such as dehydrogenases or transferases) or any other catalysts. Amendment to recite the specific catalytic unit would obviate the rejection.

E. Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim recites "variation in mass" which is unclear and indefinite. It is unclear because whether mass refer to variation in nucleotide sequence, or incorporation of labeled nucleotides or different mass labeled nucleotides Amendment to recite the specific variation in mass would obviate the rejection.

#### ***Response to Arguments***

4. Applicant's response to the office action (Paper No.9) is fully considered and deemed persuasive in part.

5. The objection made for the specification in the previous office action is withdrawn herein in view of the amendment (Paper No.9).

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6. With reference to the rejection made in the previous office action under 35 USC 112 second paragraph, Applicant's arguments with respect to claim 1-20 have been considered but are moot in view of the new ground(s) of rejection.

7. The following is the rejection made in the previous office action under 35 USC 102(b):

A. Claims 1, 9, and 15, 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Pinkel et al. (5,690,894).

With reference to the instant claim 1, Pinkel et al. teach a biochemical biosensor comprising plurality of binding partners including nucleotide sequences immobilized on its surface, and sensor surface was fabricated to measure variation in a physical parameter wherein, optical signals produced by biological binding molecules were measured on the sensor surface (see column 3, lines 1-30).

With reference to the instant claim 9, Pinkel et al. teach that the biosensor was characterized in that the sensor surface has a waveguide (optical fiber) which allows optical detection (see column 3, lines 18-30).

With reference to the instant claim 15 and 20, Pinkel et al. teach that the biological entity comprises hetero-bifunctional cross-linking agents such as antibody-ligands (biotinylated nucleic acids-antibody) (see column 19, lines 32-43). Thus the disclosure of Pinkel et al. meets the limitations in the instant claims.

B. Claims 1-2, 8, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Chai-Gao et al. (USPN. 5,858,802).

With reference to the instant claims 1-2, Chai-Gao et al. teach a biochemical sensor device or system wherein Gao et al. teach that the device comprises a biosensor for detecting or

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diagnosing a biological entity, wherein the sensor surface having detection unit comprising photoactivated coupling agent that binds with a biological entity, and the variation in a physical parameter (light emitting or absorption wavelength) which is measured at the biosensor surface (see column 1, lines 57-67, column 7, lines 1-25, column 8, lines 1-15, and column 5, lines 57-67, and column 6, lines 1-34).

With reference to claims 8, 16-17, Chai-Gao et al. also teach that the device comprises monomer compounds as oligonucleotides (see column 8, lines 6-12); compounds allowing the scaffold to be formed include homo- or hetero bifunctional crosslinking agents as immunogloblins (see column 2, lines 9-10, lines 37-51, column 5, lines 6-49).

C. Claims 1-8, and 10-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Lockhart et al. (WO 97/27317).

With reference to the instant claim 1, Lockhart et al. teach a high density arrays (biosensor arrays) comprising probe oligonucleotides immobilized on a solid support (chip) (see page 127, lines 25-32) for detecting and analyzing a biological entity in a biological sample, wherein Lockhart et al. discloses that chip surface comprises detection and measuring means to detect the hybridization signal, a physical parameter, variation in a physical parameter was measured as an indication of biological entity present in the sample (see 90, lines 5-21, page 128, lines 29-31, page 129, 1-24, page 131, lines 10-31, page 132, lines 1-2).

With reference to instant claims 2-7, Lockhart et al. also disclose that the array system includes physical parameter, which could be measured as a light wave or emission of a fluorescence signal intensity (see page 37, lines 10-22, page 127, lines 25-36, page 128, lines 1-31, page 129, lines 1-24, page 131, lines 10-31, page 132, lines 1-2); array system comprises

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DNA end labeling enzyme was a nucleic acid transferase or synthetase (see page 8, lines 3-6, page 131, lines 5-17, see page 107, lines 24-31);

With reference to the instant claims 8, 10-13, Lockhart et al. teaches that monomers of biological entity comprise fluorphor label (see page 132, lines 5-24, page 133, lines 8-12, page 135, lines 9-14, page 136, lines 1-31, page 137, lines 1-31); the sequence of nucleotides forming the detection unit was linked to the substrate by covalent bond (see page 29, lines 21-22); the immobilization of the nucleotide sequence on to the surface was carried out by photo-immobilization (see page 63, lines 8-20).

With reference to the instant claims 14-19, Lockhart et al. teaches that the nucleotide sequence forming detection unit indirectly links to the sensor surface via a docking unit which could be via avidin-conjugated fluorphore, which complexes with biotinylated target nucleic acid (see page 39, lines 24-31, page 40, lines 1-4); docking unit could include immunogloblins, enzymes, haptens (see page 41, lines 3-12); docking unit comprises partially complementary nucleotide sequence to a corresponding target nucleotide sequence (see page 49, lines 15-31, page 50, lines 1-16).

*With reference to the newly added claim 20, Lockhart et al. teach that the bifunctional molecular entity includes a hetero-bi-functional cross linking agent (silane containing fuctional group) (see page 63, lines 8-20). Thus the disclosure of Lockhart et al. meets the limitations in the instant claims.*

***Response to arguments:***

Applicant's arguments and amendment are fully considered and found not persuasive. Applicant argues that none of the prior art references teach "sufficiently high signal". Applicant further

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argue that Pinkel did not teach "a signal amplification by an increase in mass" and Chai-Gao et al. and Lockhart et al. did not teach "amplification of the signal as a result of the chain extension" and support the argument by referring to the specification. As stated in MPEP 2145, "Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims". In re Van Geuns, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993), the instant claims do not recite the limitations as discussed in the arguments and specification is not be read into the claims. Thus the rejections are maintained herein.

### ***Conclusion***

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion reached on 703-308-1119. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
July 11, 2003

  
JEFFREY FREDMAN  
PRIMARY EXAMINER